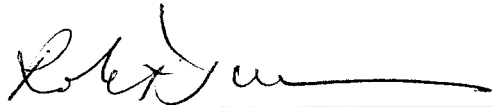


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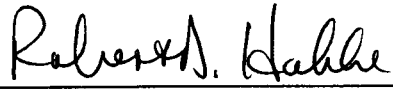
**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

**REPORT FOR AUDIT OCRWMC-BSC-04-03
OF THE CORRECTIVE ACTION PROGRAM
AT BECHTEL SAIC COMPANY, LLC
AND THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
IN LAS VEGAS, NEVADA**


JULY 6 - 12, 2004

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Date: 8/19/04

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EXECUTIVE SUMMARY

A team of auditors representing the Office of Civilian Radioactive Waste Management (OCRWM) conducted a limited-scope compliance-based audit OCRWMC-BSC-04-03 of OCRWM and Bechtel SAIC Company, LLC (BSC) in Las Vegas, Nevada, from July 6 to 12, 2004. The audit scope included an evaluation of the effectiveness of the OCRWM Corrective Action Program (CAP) as implemented through quality-affecting Administrative Procedures- (AP) 16.1Q, Revision 7, ICN 3, *Condition Reporting and Resolution*, and AP-16.4Q, Revision 3, ICN 0, *Causal Analysis and Corrective Action Plan Development*. The audit team evaluated the adequacy of these two procedures for compliance to Section 16.0, Corrective Action of the DOE/RW-0333P, Revision 14, *Quality Assurance Requirements and Description* (QARD). The audit team evaluated procedure adequacy and implementation of the CAP process steps as derived from the procedures listed in Section 1.1.

The audit resulted in the following six condition reports (CR) and two noteworthy practices. Similar conditions were grouped as appropriate to facilitate development of corrective action to preclude recurrence, and two of the six CRs were corrected during the audit:

1. CR 3208 (Level B) - Untimely identification of a CR
2. CR 3210 (Level C) - Functional evaluation not performed on nonconformance
3. CR 3194 (Level C) – Documented action for CR 2748 to issue direction to audit personnel verifying personnel qualifications before the audit was incorrect (corrected during the audit)
4. CR 3211 (Level D) - Provisions of Corrective Action Program Screening Team (CST) Charter not met (corrected during the audit)
5. CR 3195 (Level D) - Clarify AP-16.4Q for Root Cause Lesson Learned
6. CR 3196 (Level D) - Clarify basis for closure of Action 756-009 to initiate Document Action Requests (DAR) for required changes

Procedures were adequate in six of the seven process steps, and procedure implementation was effective for five of the seven process steps.

The audit team determined that the process step for Causal Analysis Determination is ineffective because procedure adequacy and implementation were unsatisfactory. AP-16.4Q describes the process for initiating, performing, and reporting results of causal analysis. The procedure is not adequate because no guidance is provided for the performance of apparent cause analysis resulting in unsatisfactory cause evaluations. The audit team did not issue a CR because BSC issued CR 3009 on apparent cause as a result of BSC Self-Assessment OSA-CAP-2004-002. Actions to address this condition are expected to be completed by August 31, 2004.

The audit team determined that implementation of the process step on Condition Report Closure was unsatisfactory due to a backlog of closed CRs that have not been processed into the Records Processing Center (RPC) and have exceeded the 60-day submittal timeframe. The audit team did not issue a CR because the CAP staff had already identified this condition in CR 2857. Actions to address this condition are expected to be completed by September 1, 2004.

In addition, the team evaluated corrective actions for previously issued CRs and found that the actions were either effective or still in process (Section 3.3).

The audit team concluded that AP-16.1Q and AP-16.4Q adequately implement the QARD requirements with the exception of the Causal Analysis Determination process step. Implementation of the process steps as derived from the procedures was satisfactory with the exception of Causal Analysis Determination and Condition Report Closure process steps. Overall, implementation of the CAP is effective.

1.0 INTRODUCTION

A team of auditors representing OCRWM performed a compliance-based audit of OCRWM and BSC in Las Vegas, Nevada, from July 6 to 12, 2004. The audit team evaluated the effectiveness of the OCRWM CAP as implemented through AP-16.1Q and AP-16.4Q. The audit team evaluated adequacy of these two procedures for compliance to Section 16.0, Corrective Action, of the QARD.

1.1 PURPOSE AND SCOPE

The audit team evaluated procedure adequacy and effectiveness of implementation of the following process steps of AP-16.1Q and AP-16.4Q:

- Identification and Implementation of Immediate Actions
- Screening and Evaluation of Condition Reports
- Causal Analysis Determination
- Corrective Action Planning
- Corrective Action Plan Implementation
- Verification of Implemented Corrective Action
- Condition Report Closure

1.2 AUDIT TEAM AND OBSERVER

Audit Team

Robert A. Toro	Navarro Quality Services (NQS)/Audit Team Leader
James E. Flaherty	NQS/Auditor
William J. Glasser	NQS/Auditor
John K. Devers	BSC/Auditor
John E. Therien	BSC/Auditor

Observer

Robert Latta	U.S. Nuclear Regulatory Commission (NRC)/Senior Resident
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2.0 AUDIT DETAILS

A pre-audit meeting was held on July 6, 2004, to review the audit scope with management. The team held daily meetings with an NRC observer in attendance to discuss the progress and status of the audit, including potential conditions adverse to quality. The audit team leader held daily meetings to inform OCRWM and BSC management of audit issues and status. The team leader conducted a post-audit meeting on July 12, 2004, to summarize the results of the audit.

Attachment 1, Summary Table of Audit Results, lists the results of evaluated process steps in AP-16.1Q and AP-16.4Q.

Attachment 2, Personnel Contacted, lists the OCRWM and BSC personnel contacted during the audit, including those who attended the pre- and post-audit meetings.

The audit team selected a sample of CRs with significance levels from A to D, including CRs from the previous CAP that were not closed by September 30, 2003, when the newer CAP process became effective. The audit team evaluated each CR for adequate implementation of each applicable process step. The team evaluated 3 of 7 Level A, 19 of 425 Level B, 16 of 361 Level C, and 11 of 694 Level D CRs. In addition, the team examined 14 Level B CRs of nonconforming conditions.

The following paragraphs describe results of the evaluation for each process step.

Identification and Implementation of Immediate Actions – As described in AP-16.1Q, the audit team evaluated any action or actions implemented at the time a condition is identified to bring the condition under process control. This process step adequately meets the QARD requirements. The audit team found two instances of noncompliance with the procedure, which resulted in CR 3208 (Level B) and CR 3210 (Level C) (see Section 3.0). However, the audit team determined that this process step was effective.

Screening and Evaluation of CRs - As described in Procedure AP-16.1Q, the audit team evaluated actions taken to determine significance and classification of the condition. This process step adequately meets the QARD requirements. The audit team identified one condition for process improvement documented as CR 3211 (Level D), which was corrected during the audit (see Section 3.0). Overall, the audit team determined that this process step was effective.

Causal Analysis Determination - The process that controls cause determination is provided in AP-16.4Q. The audit team evaluated actions taken to determine whether a root cause or an apparent cause analysis will be required based on the significance level and complexity of the condition. Implementation of this process step resulted in CRs 3194 (Level C) and 3195 (Level D). CR 3194 was corrected during the audit. A detailed description of these CRs is shown in Section 3.0. The audit team determined that the procedure is inadequate because no guidance is provided for the performance of apparent cause analysis, which resulted in unsatisfactory cause evaluations. Cause analysis determination was ineffective. Process problems in documented cause analysis were noted in 14 of 26 Levels A, B and C CRs.

The variance in quality of apparent cause analysis stems from the lack of procedural guidance in this area. AP-16.4Q directs performance of apparent cause using an appropriate cause analysis method. No other guidance is given.

The audit team did not issue a CR because BSC Self-Assessment OSA-CAP-2004-002 resulted in CR 3009, which appropriately documents and adequately addresses examples of each specific process problem noted during the audit.

Corrective Action Planning - As described in AP-16.1Q and AP-16.4Q, the audit team evaluated actions taken to document development of a corrective action plan, interim actions, remedial actions, and actions to preclude recurrence. This process step adequately meets the QARD requirements. Implementation of the corrective action planning for CRs evaluated was determined to be satisfactory. As a result, the audit team determined that this process step was effective.

Corrective Action Plan Implementation - As described in AP-16.1Q, the audit team evaluated interim actions, remedial actions, and actions to preclude recurrence are completed and documented appropriately. This process step adequately meets the QARD requirements. Implementation of the corrective action planning for CRs evaluated was determined to be satisfactory. As a result, the audit team determined that this process step was effective.

Verification of Implemented Corrective Action - As described in AP-16.1Q, the audit team evaluated the process for verifying that actions are complete including the verification of the overall CA Plan. This process step adequately meets the QARD requirements. Implementation of the corrective action planning for CRs evaluated was determined to be satisfactory. The audit team identified one condition for process improvement (Level D CR 3196 in Section 3.0). Overall, the audit team determined that this process step was effective.

Condition Report Closure – As described in AP-16.1Q, the audit team evaluated the process for closing a CR and ensuring that records for the closed CR is accurate, complete, and submitted to the Records Processing Center. This process step adequately meets the QARD requirements. Procedure implementation was determined to be unsatisfactory due to a backlog of closed CRs that have not been submitted to the RPC. Approximately 60% of the records packages for these CRs were not submitted within 60 days as required in AP-17.1Q, *Records Management*. However, the audit team did not issue a CR because the CAP organization had identified this condition in CR 2857 and is closely monitoring the issue. A September 1, 2004, goal was set to have all backlogged CRs submitted to the RPC. Overall, the audit team determined that this process step was effective.

The audit team documented the supporting objective evidence reviewed during the audit on the audit checklist, which is retained as a project record.

3.0 SUMMARY OF AUDIT RESULTS

In addition to the Condition Reports described in Section 3.1, evaluation of the process steps resulted in the following conclusions:

The audit team determined that the Causal Analysis Determination process step is ineffective because procedure adequacy and procedure implementation were unsatisfactory. The audit team did not issue a CR on this subject because BSC Self-Assessment OSA-CAP-2004-002 resulted in CR 3009.

The audit team determined that the Condition Report Closure process step was unsatisfactory for procedure implementation due to a backlog of closed CRs that have not been processed into the RPC and have exceeded the 60-day submittal timeframe. However, the audit team did not issue a CR because the CAP organization had identified this condition in CR 2857.

3.1 CONDITION REPORTS

The audit identified one Level B, two Level C, and three Level D CRs. The team also identified two noteworthy practices.

3.1.1 Level B

3.1.1.1 CR 3208 – *Untimely identification of a CR*

Requirement

AP-16.1Q, Revision 7, ICN 2, Section 1.0, states that conditions related to the quality of items associated with OCRWM work activities are to be promptly identified.

Condition

CR 2484 was issued documenting the placement of three pieces of measurement and testing equipment (M&TE) (Multimeter S/N 649536, Humidity Probe S/N S4420019, and Setra Transducer S/N 1158575) in Niche 3 without completion of an acceptance report. The M&TE was used in Niche 3 for about a month before the calibration documentation was completed and accepted. This CR was not documented in accordance with AP-16.1Q until about 11 weeks after initial identification of the condition.

3.1.2 Level C

3.1.2.1 CR 3210 - *Functional Evaluation not performed on nonconformance*

Requirements

AP-16.1Q, Revision 7, ICN 2, Paragraph 5.1, step [4], states that the CR Initiator shall document in the electronic condition report that a functional evaluation is required (if identified as a nonconformance).

AP-16.1Q, Revision 7, ICN 2, Paragraph 5.6.1, step [2], states that if the condition is a nonconformance and a Functional Evaluation has not been started, then the Responsible Manager shall direct the performance of a Functional Evaluation.

Condition

In relation to the first requirement above, 8 of 14 nonconformance CRs had either "NA" or a question mark in the functional evaluation requirement field instead of "Yes." The eight CRs were Level B nonconformances (CRs 754, 871, 1050, 1068, 2275, 2770, 2787, and 2835). Functional evaluation was performed for seven of these eight CRs.

In relation to the second requirement, CR 871 did not have a documented functional evaluation.

3.1.2.2 CR 3194 – Documented action for CR 2748 was incorrect (Resolved/Closed, corrected during the audit)

Requirements

AP-16.1Q, Revision 7, ICN 2, Section 5.6.1, step [16], requires that the Responsible Manager assign and document any remedial actions and actions to preclude recurrence in accordance with the Corrective Action Plan.

AP-18.3Q, *Internal Audit Program*, Revision 2, ICN 0, Section 5.2, step [4], requires that the Audit Team Leader ensure that each potential Audit Team Member is qualified as required by AP-18.1Q, Revision 1, ICN 0, *Audit Personnel Qualification*. The Audit Team Leader must perform this step before audit plan preparation.

Condition

CR Action 2748-001 requires that the Audit and Surveillance Supervisor issue direction to audit personnel regarding the above requirement to be completed before the audit itself. The audit team member noted that CR Action No. 2748-001 does not address the requirement to verify personnel qualifications before issuance of the audit plan.

The condition was discussed with the BSC Audit and Surveillance Supervisor, who reissued the correspondence to correct the point of compliance from "prior to audit" to "creation of the audit plan." In addition, a notation was added to the reroute note of CR 2748 to explain the need for the change. No other instances of this condition were noted. The audit team verified that the revised communication (electronic mail) properly described the requirement, confirmed the explanation in CR 2748 before closing this condition during the audit.

3.1.3 Level D

3.1.3.1 CR 3211 - Provisions to Corrective Action Program Screening Team (CST) Charter not met (corrected during the audit)

Requirement

None - Section III of the *Corrective Action Program Condition Screening Team (CST) Charter*, Revision 6, specifies that the CAP Manager maintain a memorandum on current CST membership. The CST Charter is not a requirements document. The CST serves in an advisory capacity.

Condition

No memorandum existed as specified by CST Charter. However, an undated printout identifying CST members was provided to the audit team. The printout did not identify current members. In addition, the printout did not identify a CST representative from the Office of Performance Management and Improvement (OPMI) as specified in the CST Charter organizational representative matrix. Review of Revision 7 of the CST Charter indicated that the CAP Manager will maintain a current listing of CST membership and their organization affiliates in a file separate from the CAP system. A dated CST membership list (including the OPMI representative and alternative) is also available on the CAP database. This condition was resolved and closed during the audit.

3.1.3.2 CR 3195 - Clarify AP-16.4Q for Root Cause Lesson Learned

Requirement

None

Condition

Root Cause Analysis Reports do not document Lessons Learned or generic implications. Instead, there is an electronic CAP form for this need. AP-16.4Q should be revised to indicate clearly that documentation in the electronic CAP is an acceptable alternative to documentation in the report.

3.1.3.3 CR 3196 - Clarify basis for closure of Action 756-009

Requirement

None

Condition

The subject of CR Action No. 756-009 is to initiate DARs for required procedure changes. The Action Description is to initiate DARs to track affected procedure development/revision. The Action Taken section indicates that DARs were created to ensure that requirements are properly captured. However, the DARs were created not to manage a procedure change but rather to request a review of affected procedures. This is not the intended use of a DAR, which should be generated only after a review indicates a need for a change.

It is recommended that the closure statement be supplemented to explain that the subject DARs do not request a procedure change to meet the QARD but only a procedure review.

3.2 NOTEWORTHY PRACTICES

CST Meetings

The agendas for the CST meetings are well structured. The participants were prepared and knowledgeable of the conditions being discussed, and the team interactions were excellent.

Cause Analysis

The cause analysis for CR 792 identified a specific set of cause codes. During processing of this CR, the codes were revised. The Responsible Manager provided clear documentation in the reroute notes to explain the reason for the change. This is considered an excellent practice.

3.3 FOLLOW-UP TO PREVIOUSLY COMPLETED CORRECTIVE ACTIONS

The following previously identified and closed CRs were reviewed to verify continued effectiveness of completed corrective actions.

CR 1294 (Level B)

Condition

This CR identified that the CR screening process does not provide adequate classification of the significance or identification of the proper cause codes.

Follow-up Results

Investigation determined that trend codes were updated in CRs, the CAP staff was trained on the definition of the event and cause codes, and the review requirements as documented in AP-16.1Q were reiterated to the CST. No similar repetitive conditions were identified during this audit. The audit team determined that the corrective action was effective.

CR 1957 (Level C)

Condition

This CR identified incomplete CR records package signatures and dates.

Follow-up Results

A memorandum to all affected records was submitted to the Records Center to address noncompliance for the CAP Manager entries. The CAP staff plan to conduct an analysis of closed records on a quarterly basis. No similar repetitive conditions were identified during this audit. The audit team determined that the corrective action was effective.

CR 1958 (Level D)

Condition

This CR identified the lack of a requirement in AP-16.1Q to establish goals or tracking to ensure that the electronic record is printed and processed to the RIS.

Follow-up Results

A tracking system was established for the CAP Group to track records submission. Performance against the goal that will be established is monitored using this tracking system. The audit team determined that this action is complete. In addition, the CAP Group issued CR 2857 due to backlogged CRs not submitted to the RPC. A goal of September 1, 2004 was set to address all backlogged CRs submitted to the RPC.

CR 2611 (Level B)

Condition

This CR identified that the CR Requirements field entries often do not specify the requirements document related to the condition, including section and paragraph number(s).

Follow-up Results

AP-16.1Q was enhanced to state clearly that Level A, B, or C CRs must reference the requirements document, including the section and paragraph and that the Requirements field in the database must be completed before processing. No similar repetitive conditions were identified during this audit. The audit team determined that the corrective action was effective.

CR 2613 (Level D)

Condition

This CR identified three areas in AP-16.1Q to be clarified or improved. First, there was no requirement to show revision number when a related requirements document is noted in the Requirement field. Second, the procedure was not clear on how a related requirements document is noted when a CR is elevated from a lower level to a higher level. Third, the procedure was ambiguous on who has responsibility for determining the Unknown related documents before a CR is issued.

Follow-up Results

This condition as well as the necessary corrective actions have been incorporated and addressed in CR 2540. No similar repetitive conditions were identified during this audit. Evaluation of corrective action was not conducted because CR 2540 had not reached the verification phase.

3.4 PROGRAM ADEQUACY, IMPLEMENTATION, AND EFFECTIVENESS

The audit team concluded that AP-16.1Q and AP-16.4Q adequately implement QARD Section 16.0, Corrective Action. Overall, implementation of the CAP was effective. Procedure adequacy was effective in six of the seven process steps, and procedure implementation was effective for five of the seven steps, as discussed in Section 2.0 of this report.

4.0 ATTACHMENTS

Attachment 1 – Summary Table of Audit Results

Attachment 2 – Personnel Contacted

ATTACHMENT 1

SUMMARY TABLE OF AUDIT RESULTS

Process Steps (Procedure)	Condition Reports (Level A)	Condition Reports (Level B)	Condition Reports (Level C)	Condition Reports (Level D)	Noteworthy Practices	Procedure Adequacy (S or U)	Procedure Implementation (S or U)	Effectiveness (E or I)
Implementation of Immediate Actions (AP-16.1Q)		CR 3208	CR 3210			S	S	E
Screening and Evaluation of Condition Reports (AP-16.1Q)				CR 3211 (CDA)	NP1	S	S	E
Causal Analysis Determination (AP-16.4Q)			CR 3194 (CDA)	CR 3195	NP2	U*	U*	I*
Corrective Action Planning (AP- 16.1Q and AP-16.4Q)						S	S	E
Corrective Action Plan Implementation (AP-16.1Q)						S	S	E
Verification of Implemented Corrective Action (AP-16.1Q)				CR 3196		S	S	E
Condition Report Closure (AP- 16.1Q)						S	U**	E

OVERALL EFFECTIVENESS OF PROGRAM: **EFFECTIVE**

* = Procedure was not adequate because performance of apparent cause analysis resulted in unsatisfactory cause evaluations. No CR was issued for this process because BSC Self-Assessment OSA-CAP-2004-002 resulted in CR 3009.

** = Unsatisfactory due to a backlog of closed CRs that have not been processed into the RPC and have exceeded the 60-day submittal timeframe. No CR was issued because the CAP organization identified this condition in CR 2857.

Legend:

CR = Condition Report CDA = Corrected During Audit NP = Noteworthy Practice
S = Satisfactory E = Effective I = Ineffective U = Unsatisfactory

Attachment 2 – Personnel Contacted

Name	Organization	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Andrew Burningham	BSC RD		X	
Mike Carmichael	BSC OA	X	X	X
Mike Collins	BSC OA	X	X	X
Tom Esper	BSC QA	X	X	X
Judy Gebhart	BSC QA		X	
Gary Grant	BSC QA			X
Hank Greene	BSC QA	X		X
Bob Habbe	BSC QA	X		X
Steve Harris	BSC QA		X	
Bob Hartstern	BSC QA	X	X	X
Bill Holub	BSC QA	X		X
Mike Mason	BSC QA			X
Danika Miller	BSC OA		X	
Richard Powe	BSC QA	X		X
Steve Schuermann	BSC QA			X
Steve Swenning	BSC OA		X	
Teri Vincent	BSC OA	X	X	X
Ken Wolverton	BSC ES&H			X
Carl Wright	BSC QA			X
C. Dennis Sorensen	BSC OA			X
Yvonne Tsang	LBNL		X	
Frank Kratzinger	MTS	X		
Jim Harper	MTS	X		X
Marilyn Kavchak	NQS	X		X
Denny Brown	OQA	X		
Kerry Grooms	OQA	X	X	X
Michael Valentine	ORD/OPMI	X		X
Richard Spence	ORD/OPMI	X	X	X

Organization Legend:

BSC	Bechtel SAIC Company, LLC
ES&H	Environmental Safety & Health
MTS	Management Technical Services
NQS	Navarro Quality Services
OPMI	Office of Performance Management and Improvement
OQA	Office of Quality Assurance
OR	Organizational Assurance
ORD	Office of Repository Development
QA	Quality Assurance
RD	Repository Development